



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE BOARD OF PHARMACY
MEETING MINUTES
October 30, 2008

Department of Health Kent Offices
Marketing Center Creekside Three
at CenterPoint
20435 72nd Ave S, Suite 200
Kent, Washington 98032
Reception Desk (253) 395-6791

CONVENE

Chair Rebecca Hille called the meeting to order at 9:03 a.m., October 30, 2008.

Board Members present:

Rebecca Hille, BA-Public Member
Albert Linggi, RPh
Dan Connolly, RPh
Rosemarie Duffy, RN, MA, MSN, Public Member

George Roe, RPh
Gary Harris, RPh Vice-Chair
Vandana Slatter, PharmD

Staff Member present:

Joyce Roper, AAG
HSQA
Steve Saxe, RPh, Executive Director(Acting)
Lisa Hodgson, Executive Manager
Grant Chester, Chief Investigator
Association
Grace Cheung, Investigator
Cathy Williams, Pharmacist Consultant
Tim Fuller, Pharmacist Consultant
Doreen Beebe, Program Manager
Leann George, Program Support

Guest / Presenters

Karen Jensen, Assistant Secretary for
Matt Shellar, VP of Operations for
Insty-Meds
Rod Schafer, Executive Director of
Washington State Pharmacy

Grady Clapp, Washington State
University PharmD Intern
Bill Osmunson, DDS, MPH,

Mission Statement

The mission of the Board of Pharmacy is to achieve the highest standards in the practice of pharmacy and promote public health and safety and to effectively communicate with the Governor, Legislature, the Department of Health, the public and profession.

Vision Statement

The Washington State Board of Pharmacy leads in creating a climate for the patient-focused practice of pharmacy.

We support and encourage our pharmacists to inform, educate, consult, manage drug therapy and provide products as an integral part of an accessible, quality-based health care system.

As a result, the citizens of Washington State:

- Are well informed about medications;
- Take responsibility for their health;
- Utilize pharmacists and other health care providers appropriately; and
- Experience the highest level of health and wellness

PRESENTATIONS

Health System Quality Assurance – Reorganization

Karen Jensen, Assistant Secretary for HSQA and Steven Saxe, Director of Health Professions and Facilities updated the Board on the division's reorganization. Karen Jensen began by introducing herself and her role as the newly appointed Assistant Secretary. Ms. Jensen spoke about the recommendations of the 2006 performance audit and the intended goals of the reorganization.

- Improve patient safety.
- Increase public confidence in our ability to protect public health.
- Build thorough approach to system improvements.
- Seamless and efficient delivery of services.

In addition to the reorg, HSQA implemented a new computer system - Integrated Licensing Regulatory System (ILRS) As a result, telephone calls have increased and processing times for credentials were significantly impacted. HSQA staff have worked diligently in reducing call wait times and the number of calls dropped (lost), and meeting issuing target timelines for credentials.

What's next for the division?

- Follow-up performance audit scheduled for December 2008
- Strategic planning to include: business structure, emergency preparedness, space planning and budget planning.
- Provide employees more tools and training, with clear expectation and accountability.
- Discuss operating agreements with the Department of Health and boards and commissions.

CONSENT AGENDA

1.1 Pharmacist License Application Approval.

- Michael W. Hoffner – Nuclear Pharmacist

1.2 Pharmacy & Other Firm Application Approval.

- New and Closed Pharmaceutical Firms 8/12 – 10/9/2008

1.4 Pharmacy Tech Training Program Approval.

- Virginia M. Kelly – Santa Rosa Junior College, Santa Rosa CA
- Deanna Lee Goodman – MCED Career College, Fresno CA
- Veronica M. Romero – Milan Institute, Sparks NV
- Northeast Washington Medical Group Pharmacy – CF56735
- Kaulahea Wilcox – Foodland Pharmacy HI

1.5 Collaborative Drug Therapy Agreement Acceptance

- Asaad Awan – Tulalip Pharmacy – Suboxon
- Cameron R. Santer – Bartell Drugs #67 – Motion Sickness
- Cameron R. Santer – Bartell Drugs #67 – Anti-Malaria Prophylaxis
- Cameron R. Santer – Bartell Drugs #67 – Epi-Pen
- Cameron R. Santer – Bartell Drugs #67 – Traveler's Diarrhea
- Cameron R. Santer – Bartell Drugs #67 – Altitude Sickness
- Joseph Johnson – Bartell Drugs #65 – Epi-Pen
- Joseph Johnson – Bartell Drugs #65 – Altitude Sickness
- Joseph Johnson – Bartell Drugs #65 – Traveler's Diarrhea
- Joseph Johnson – Bartell Drugs #65 – Anti-Malaria Prophylaxis
- Gary Lagerstrom – Bartell Drugs #38 – Anti-Malaria Prophylaxis
- Gary Lagerstrom – Bartell Drugs #38 – Motion Sickness
- Gary Lagerstrom – Bartell Drugs #38 – Traveler's Diarrhea
- Miyuki Anderson – Bartell Drugs #61 – Cold Sores
- Miyuki Anderson – Bartell Drugs #61 – Silver Sulfadiazine
- Steven F. Anderson – Bartell Drugs # 31 – Cold Sores (in notebook twice)
- H. John March – Fed Meyer Pharmacy #385 – Malaria & Traveler's Diarrhea
- Robert Keller and Paul Diment – Mill Plain Medical and Pharmacy – Motion Sickness
- Various Pharmacists – CHC of Snohomish County – Bedtime Insulin Protocol & Titration
- Various Pharmacists – CHC of Snohomish County – SMBG Glucometer Test Strip
- Various Pharmacists – Jones Pharmacy and Home Health Care – Initiation of Antiviral Therapy for Influenza A and B
- Various Pharmacists – Capital Med Ctr – Anticoagulation
- Don Briggs – Evergreen Healthcare – Insulin Pen Device
- T. Renee Freitag – Providence Regional Cancer Partnership – Anemia Management

1.8 Board Minute Approval - September 4, 2008

Items listed under the consent agenda are considered to be routine agency matters and will be approved by a single motion of the Board without separate discussion. Items 1.3 -Pharmacy Technician Application Approval and 1.7 –Sample Drug Distribution Requests were deleted from the agenda.

Gary Harris requested to discuss item 1.6 – Use of Automated Drug Distribution Devices submitted by Shick Shadel separate from the other consent agenda items.

MOTION: George Roe moved that the board approve items 1.1, 1.2, 1.4, 1.5, and 1.8. Gary Harris second. **MOTION CARRIED:** 6-0.

- 1.6 Gary Harris shared his concern that Shick Shadel's policies and procedures for the use of Pyxis dispensing systems did not verify that the removal of discharged and deceased patients from the database. Tim Fuller assured that there time for removal was less than 12 hours.

MOTION: Gary Harris moved that the board approve item 1.6 with the inclusion that former patients be removed from database within 6 hours. George Roe second. **MOTION CARRIED:** 6-0.

REPORTS

Board Member

Dan Connolly reported:

He attended a few different meetings

- Stakeholder meetings/workshops on rules for correctional facilities/pharmacies.
- Prescription Monitoring Program (PMP) stake holder workshop in Kent, WA.
- The Governor's Committee in illicit prescription drug use.

Gary Harris reported:

- He attended the initial informational meeting of Medication Use Management Program. There are some concerns regarding securing access to the database used for documenting medication therapy management services. There was enthusiasm to get the program running

Rebecca Hille reported:

- She participated in the PMP informational meeting in Spokane, WA.
- Rebecca also attended the PMP stakeholder workshop in Spokane, WA. There were 15-17 participants at the workshop which was better than the informational meeting.

Rosemarie Duffy reported:

- September 11, 2008 Rosemarie was able to attend the Investigators Meeting in Tumwater, WA. What a wonderful group of people to work with.

Executive Director

Steven Saxe reported:

- Steve and Karen Jensen are spending time with all board and commissions to provide an update on activities within Health System Quality Assurance (HSQA). There has also been a lot of work back at the office coordinating the physical moves of the reorganization.
- November 7, 2008 there will be a board and commission meeting to get feedback on what we need to work on with this reorganization.
- Still in the energy and expenditure reduction and the hiring freeze.

- Department of Health is moving forward in the search of a Pharmacy Executive Director.
- He has been involved in state strategic health planning.
- Steve has been participating in Tribal review for health facilities on tribal properties run by tribal organization. We don't license them but we have the skill and expertise to help. This will impact on pharmacies he will keep the board informed.
- There is more work with product return and product stewardship as it relates to the pilot the department has been involved in. There will be legislation again next year.
- He had an opportunity to attend Washington State Hospital Association meeting on patient safety and quality improvement.
- Tim Fuller, Chris Baumgartner and Steve Saxe appeared before the Senate Health and Long Term Care Committee to provide an update on e-prescribing (electronic prescribing) and the prescription monitoring program.
- Steve acknowledged Rod Schafer for his role with the Washington State Pharmacy Association and wished him continued success with his move to California.

Assistant Attorney General

Joyce Roper reported:

- She updated the board on the Storman's case. The case has had a number of motions going back and forth. Lisa Salmi was deposed as a board representative. There are notices issued for three board members and four staff members.

Consultant Pharmacists

Tim Fuller reported:

- Updated the health committee senators on e-prescribing.
- Tim has been working on cross profession issues. Veterinary Technicians became licensed last year. The Veterinary Board of Governors sought help on how to enumerate their functions within the dispensing process.
- He has also been working with Occupational Therapist who may now use medications.
- Tim Fuller introduced Grady Clapp and asked him to share his experience with the board.

Grady Clapp:

Grady shared a general overview on his time spent as an internship. Half of his time was spent at the Department of Health. The other half of his time was spent in the field with some investigators.

Department of Health

- Reviewed pharmacist prescriptive authority protocols, e-prescribing protocols, electronic dispensing protocols.
- Researched questions relayed to pharmacist consultants.
- Grady received an overview of HSQA organization and a tour of the pharmacist application process.
- He participated in the Prescription Monitoring Program workshops.
- Spent a day at the legislature in Olympia, WA.

Pharmacist Investigators

Jim Doll:

- Inspected Target Pharmacy and Fife Pharmacy and Gifts.
- Visited telepharmacy sites for Community Health Care.
- Attended portion of Meth Summit in Tacoma.

- Visited drug court.
- Visited Western State Hospital.

Stan Jeppesen:

- Sorted and prepared medications for shipping at Group Health Pharmacy in Tukwila.
- PH:ARM program research in Seattle.
- Reviewed protocols under review for two boarding homes.

Jim Lewis:

- Inspected Elma HealthMart Pharmacy.
- Visited Washington Corrections Center for Women in Gig Harbor.

Dick Morrison:

- Inspected Sarvey wildlife refuge, instructed the managerial staff on proper storage and documentation of drugs and controlled substances.
- Visited a strategic national stockpile site in Everett.
- Inspected Costco central fill and mail order pharmacies in Everett.

Bill Kristin:

- PMP rulemaking workshop in Spokane, WA.

Greg Lang:

- Inspected Pacific Medical Center outpatient surgery center and outpatient in Seattle.
- Inspected Pacific Drug independent pharmacy in downtown Seattle.

Grady touched on three points this rotation provided for him. This was a really unique experience, researching the laws and answering questions turned out to be great preparation for the MPJE. Listening to the Pharmacist Consultants and Investigators views and philosophies on the profession helped him understand the future of pharmacy and his career. He thanked everyone for this opportunity.

Chief Investigator

Grant Chester reported:

- Pharmacist investigators are up to date on performance evaluations, performance plans, work schedules and position description.
- Jim Doll and Doreen Beebe are still working together on the correctional facilities rules.
- Grant met with Immigration and Customs Enforcement Group Supervisor. The meeting was for Grant to be updated on their efforts to halt the importation of counterfeit drugs into the Northwest and to ask for support.
- Stan Jeppesen is involved in the wind down of PH:ARM pilot program that will continue until the end of the year.
- Grant gave an update of the number of inspections performed and the number of investigations. Both are down for the month. A big part of it is from Joe Honda being retired.

Program Manager

Doreen Beebe reported:

- There will be five board members who will be attending the boards and commission forum November 7, 2008.
- Washington Recovery Assistance P Program is holding an orientation for Gary Harris, Al Linggi and Vandana Slater December 19, 2008.
- There has been three CR105 expedited rule packets filed.

1. Pharmacies must have access to current Washington Pharmacy law – not restricted to printed law book.
 2. WAC 246-869-090 correction to reference number citing Code of Federal Regulations
 3. Updating the reference for designating legend drugs - Drugs Topics Red Book – 2008 edition WAC 246-883-020- still in comment period.
- Pharmacy Technician Education and Training rule amendments were filed October 24, 2008. The rule changes are effective January 1, 2009.
- Spoke with Judy Hanke regarding the veterinary board assistance once the board initiates the process to consider rules regarding animal control and human society rules.

PRESENTATIONS cont'd

InstyMeds

Cathy Williams provided brief background on the proposal by Cascade Valley Hospital to use the InstyMeds automated prescription medication dispensing system in their emergency department. The proposal was presented by InstyMeds' VP of Operations, Matt Sneller, and, Ed Rikert, InstyMeds' Chief Council. Cascade Valley's Assistant Administrator of Patient Care Services was also present to answer questions.

Highlights:

- There are currently 125 machines in use across the U.S.
- To date 500,000 medications have been dispensed without error.
- Access to a pharmacist via a phone connection on the dispensing device is available 24/7. The pharmacist is located in Minneapolis, where InstyMeds is based.
- Patients are given a unique seven-digit access code for a one-time access to the device. Each Prescription is checked by a three barcode process before it is dispensed to the patient.
- The goal is to provide medications to patients when the pharmacy is not open or when inpatient pharmacy services are limited (there is no outpatient pharmacy).
- The system is based on a physician dispensing model.

Concerns:

- Use of InstyMeds system when the pharmacy is open
- Meeting requirements for patient counseling.
- Conflicts with WAC 246-873-050 – Hospital Standards.
- Requirement for Washington licensure for the non-resident pharmacist.

MOTION: George Roe moved to deny the request for InstyMeds to provide Cascade Valley Hospital automated service. Gary Harris second. **MOTION CARRIED:** 5-1. Dr. Vandana Slater opposed.

Rosemarie Duffy asked that we look at the Hospital rules in the next board meeting.

WSPA – Quality Improvement Program

Rod Schafer, Executive Director of Washington State Pharmacy Association presented their quality improvement program designed for community pharmacies. (Pharmacy Quality

Commitment®) Rod Schafer. He introduced Jeff Rochon, named **interim** CEO during the search process.

His presentation began with a little background of the material. First report came out in 2000 "To Err is Human". Medicines dirty little secret came out about the health care system it was unsafe and there were a lot of problems people were dying. It was looked at as a systems issue not necessarily a people issue. In 2001 "Crossing the Quality Chasm" came out. The purpose for this report was there was awareness of the issues no one did anything about it. With a look into specific issues that caused a lack in quality care for patients. 2006 a report about "Medication Errors" was written. This discussed the amount of adverse events per year in hospitals. This is an issue that really needs to be addressed.

Rod Schafer shared Pharmacy Quality Commitment and the benefits it would have for patient safety and quality care.

- The purpose of this is to prevent "near misses" in dispensing medications.
- Health care is very complex.
- Build redundancy to reduce a chance of error. (build a check list)
- There are many errors in pharmacy.
- Most of them have to do with mechanical issues.
- Pharmacist being sued even if a prescription is filled correctly.
- Reason is for this is because prescription should not have been filled in the first place.
- These could be preventing by building a system.

The National Alliance Pharmacy Association thought this was an important issue and purchased the right to this in 2004. This is not a one size fits all program. It needs to be made to fit every situation. This is a very effective system when done by a pharmacy technician.

This product has two components.

The Sentinel Workflow System

- Manual
- Workflow
- Best practice techniques

The Quality Manager Quality-Related Event (QRE) online reporting system

- Data Collection
- QRE collection forms
- QRE Data Entry
- Charts, Graphs and spreadsheets
- Evaluations and steps for improvement

He discussed an example step by step. The key to a system is to report data. Using past data helps to know what areas to improvements.

There are about 103 pharmacies using this product and about 5,000 across the country. This is a yearly subscription program.

EXECUTIVE SESSION (Closed Session)

The board adjourned for closed session at 12:13 p.m. and reconvened at 1:32 p.m.

PRESENTATION cont'd

Fluoride

Bill Osmunson DDS, MPH provided an informational presentation on concerns regarding water fluoridation. Dr. Osmunson asked that the board give consideration to designating fluoride substance as a poison and required that fluoride used for the mitigation of human disease be dispensed as a legend drug.

DISCUSSION

Rule Making

Lisa Salmi and William Rhodes, WRAPP Program Manager asked the board to consider amending WAC 246-867 Impaired Pharmacist Rehabilitation to change the requirements for random drug testing. . WRAPP asked that the board allow for unobserved urine analysis collection provided that there are safeguards to ensure that the collection is trustworthy.

The discussion included requiring samples within 12 hours rather than the current 24 hours if deemed necessary. There were concerns expressed by meeting observers that this may cause a hardship for pharmacist who work extended hours (10 – 14 hour shifts).

MOTION: Rosemarie Duffy moved that the board initiate the rulemaking process to amend WAC 246-867. Gary Harris second. **MOTION CARRIED:** 6-0.

Board of Pharmacy Procedures

The board discussed proposed procedure # 36 *Internship Registration for Participation in a Residency Program* for approval. The procedure will provide a process for graduates of accredited schools or colleges of pharmacy to qualify for a Washington Pharmacy Intern License to participate in a residency program for Rebecca Hille briefed the rest of the board on this matter. There are graduates who are going to residency who come from out of state and don't want a Washington State Pharmacy License.

MOTION: Dan Connolly moved the board accept the procedure for Internship Registration for Participation in a Residency Program. Al Linggi second. **MOTION CARRIED:** 6-0.

Case Presentations/Authorizations

The Board discussed setting a new day/time for case presentation conference calls or other means to distribute cases to members that are unavailable.

MOTION: Rosemarie Duffy moved that the board change the day/time for case presentation conference calls to Friday's at 10 a.m. George Roe second. **MOTION CARRIED:** 6-0.

Final Orders

Bill Kellington began the discussion regarding compliance language on final orders and "probation" designated on credentials. Historically pharmacy has chosen not to display a probationary status or license restriction on a pharmacist's license. Pharmacist license are to be displayed and it may cause a problem with a patient who sees "Probation" on the license.

- This can provide as a tool for credentialing and discipline cases.

- Integrated Licensing Regulatory System (ILRS) can default to print restrictions on a license.
- All other order compliance cases are now being worked through ILRS.

Bill asked the board if they would like to have these restrictions placed on a pharmacist's credential. He offered sample and more discussion if the board had concerns or questions.

MOTION: Rosemarie Duffy moved the board allow Active on Probation be amended to Active with Restrictions to be written at the bottom of a pharmacist's license where it is applicable. Dan Connolly second. **MOTION CARRIED:** 6-0.

CORRESPONDENCE

The following correspondence was reviewed and discussed by the board.

- NABP State News Roundup – August 2008 NABP – Formal complaint filed with the Accreditation Council for Pharmacy Education regarding the accreditation status of the University of Georgia, College of Pharmacy
- NABP – Technician Certification Examination – NABP addressed questions regarding the Pharmacy Technician Certification Board (PTCB) and the Institute for the Certification of Pharmacy Technicians (ICPT).
- DSHS News Release - Written Medicaid prescriptions must meet new special tamper-resistant standards beginning October 1, 2008
- NABP state News Roundup – September 2008
- NABP eNews – October 2008
- NABP – Internet Drug Outlet Identification Program – Progress Report 10/2/08

OPEN FORUM

Colin Conway from Group Health shared a question regarding one of the FDA amendments act passed a few years ago on provision was inclusion of the adverse events line for every single prescription. He hasn't heard much about it lately. How is this supposed to be interpreted? Is this a board of pharmacy issue? Is it a FDA issue?

Dan Connolly responded that as of Tuesday October 28, 2008 FDA postponed this until July 2009 because of the rule process. Interpretation is whether it should be on label is up to an individual it is not a state regulation it is a Federal regulation. Bartell's will be putting it on their label. We do not have a RCW or a WAC that allows us to take action on this subject.

Audrey Adams is a mother of an autism child. She shared her personal story regarding fluoridation in our water. She has discovered her child has a chemical sensitivity. It took her many years to realize this sensitivity her son has. Through many years of taking all chemicals out of her son's life her son still had severe headaches. A friend of hers asked her about the water being fluoridated. After taking this away from her son he still had headaches. She realized that his showers were causing his headaches because there is fluoridation in our water systems. She began bathing him herself with non fluoridation water his headaches stopped. She is filing a complaint through the board of pharmacy against Seattle Public Utility who adds the fluoride to water without a license to practice. She asked the board read her complaint.

Linda Martin another resident of King County read her statement regarding her and her son's reactions to fluoridated water. Linda and her son have gone through great trouble and expense to avoid fluoridated water. They have had to move several times to get away from water systems that have fluoridated water. She is afraid she is going to have to move again and it is difficult to have to keep doing this.

Al Linggi wanted to go on record that he works with McKesson who provides prescription monitoring programs and services. Since the department is working on a prescription monitoring program this causes a conflict of interest. Because of this he will not be involved at all or attending any meetings regarding the states program.

Rod Schafer has an issue that comes up with Tamper resistant pads. He would like someone to put together a housekeeping component so a pharmacy /pharmacist can tell the prescription is tamper resistant. He mentioned that New York pays for the pads that are serialized that does cost a bit but saves in the long run.

Gary Harris asked that we spend more time at each board meeting on our Rules Update.

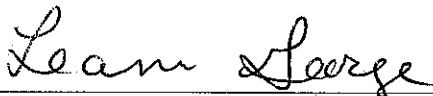
BUSINESS MEETING ADJOURNED

There being no further business, the board adjourned at 4:37 p.m. The Board of Pharmacy will meet again on December 11, 2008 for its regularly scheduled business meeting in Kent, Washington.

PRESENTATION OF AGREED ORDERS

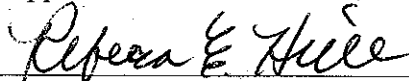
CLOSED SESSION

Respectfully Submitted by:



Leann George, Program Support

Approved on December 11, 2008



Rebecca Hille, Chair

Washington State Board of Pharmacy